DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

(b) (4)
Attention: (b) (4) Principal
U.S. Agent for: PharmaTher Inc.
4237 Barnes Meadow Road, SW
Smyrna, GA 30082

RE: ANDA 217858
KETAMINE HYDROCHLORIDE injection, for intravenous or intramuscular use, CIII
MA 2

Dear (b) (4)

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, the "Products" webpage (webpage)[1] for KETAMINE HYDROCHLORIDE injection, for intravenous or intramuscular use, CIII (Ketamine[2]) on the website for PharmaTher Inc. (PharmaTher). FDA has determined that the webpage is false or misleading. Thus, the webpage misbrands Ketamine and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The webpage includes claims and/or representations about the benefits of Ketamine but fails to communicate **any** risk information. By omitting the risks associated with Ketamine, the webpage fails to provide material information about the consequences that may result from the use of Ketamine and creates a misleading impression about the drug's safety.

The webpage includes the following claims and representations (in pertinent part):

- "With the recent FDA approval of KETARx™ for surgical pain management (anesthesia and sedation for surgical and diagnostic procedures)…"
- "KETARx™ Ketamine Portfolio" visual that describes this product as being FDA-approved for "Pain and Surgery Management"

These broad claims and representations are misleading because they fail to provide material information regarding Ketamine's full FDA-approved indication. Specifically, the INDICATIONS AND USAGE section of the FDA-approved Prescribing Information (PI) states the following (underlined emphasis added):

Ketamine Hydrochloride Injection is indicated:

[1] "Products" webpage located at https://www.pharmather.com/products.html (last accessed September 18, 2025)
[2] Referred to as "KETARx™" on the "Products" webpage

- as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation.
- for the induction of anesthesia prior to the administration of other general anesthetic agents.
- as a supplement to other anesthetic agents.

The webpage suggests the use of Ketamine in all surgical and diagnostic procedures, but it does not specify its use in procedures that do not require skeletal muscle relaxation; for anesthesia induction prior to other general anesthetics; or as a supplement to other anesthetics. Furthermore, by referring to the FDA approval as "for surgical pain management" or for "pain and surgery management," these broad claims and representations misleadingly suggest that the FDA-approved indication is different from the reference listed drug (RLD), Ketalar Injection 200 mg/20 mL (10 mg/mL). This is particularly concerning given that Ketamine was approved as a 505(j) application demonstrating bioequivalence to the RLD and shares the same FDA-approved indication. By failing to adequately communicate the indication for Ketamine, the webpage creates a misleading impression about the drug's FDA-approved indication.

FDA regulations require any labeling or advertising devised for promotion of the drug product to be submitted at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. A copy of the webpage was not submitted to FDA under cover of Form FDA-2253 at the time of initial publication as required.

Conclusion and Requested Action

For the reasons described above, the webpage misbrands Ketamine and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that PharmaTher take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Ketamine that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Ketamine.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 2 in addition to the ANDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Phillip Williams, PharmD, RAC
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Samuel Skariah, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PHILLIP A WILLIAMS
09/30/2025 10:18:04 PM

SAMUEL M SKARIAH
09/30/2025 10:21:13 PM